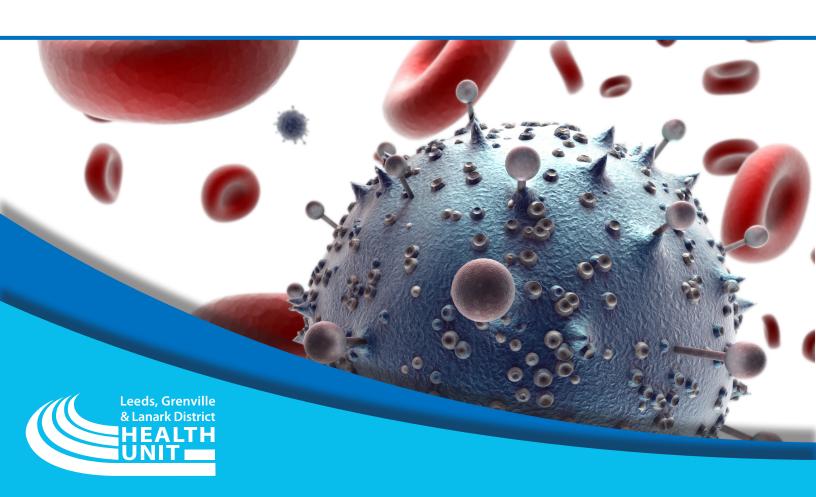
5-Step Quick Reference P.E.P.

Clinical management of non-occupational and occupational exposure to Hepatitis B, Hepatitis C and HIV



Introduction¹

This document provides guidance to health care workers (HCWs) in Leeds, Grenville and Lanark Counties who are called upon to assess and manage incidents of exposures (percutaneous, mucosal or non-intact skin) to blood or body fluids that are capable of transmitting hepatitis B (HBV), hepatitis C (HCV), or human immunodeficiency virus (HIV).

This 5 step framework developed by St. Michael's Hospital (Pocket P.E.P. Reference), provides guidance in assessing and managing blood or body fluid exposures.

Exposed individuals may include health care workers or emergency service providers, who in the course of their duties accidentally sustain an injury which could mean a potential exposure. Additionally, others from the community may seek help for exposures such as blood splashes, bites, sexual exposures, accidental needle sticks or exposures within health care settings. Official guidance for hospitals in designing their response protocols for internal occupational exposures remains with the OHA/OMA - MOHLTC protocol.

Each instance of a possible exposure to HBV, HCV or HIV must be assessed carefully and quickly. In most instances this is best done in an emergency department or urgent care setting. Where an exposure is determined to be significant, treatment with **post-exposure prophylaxis (PEP)** for HBV and/or HIV may be warranted, and if so, should be started as soon as possible (for HIV PEP this is ideally within 2 hours).

Role of the Health Unit¹

Health Unit staff provide information, education and support in consultation with the Medical Officer of Health, including help to assess the risk of the exposure. Recommendations for testing and care may also be made; however, decisions related to care ultimately rest between the individual and their health care provider.

Contact the Health Unit as follows:

During regular office hours, Monday through Friday 8:30-4:30 call the Brockville office at 613-345-5685 or the Smiths Falls office at 613-283-2740 and speak to a nurse on the Infectious Disease team. After hours, on holidays and weekends, call our answering service at 613-345-5685.

The information above is adapted with permission from Simcoe Muskoka District Health Unit, 2014.

An individual who experiences an occupational or non-occupational exposure to potentially infectious blood or body fluids needs to have immediate first aid treatment for any wound and a risk assessment for the likelihood of transmission of a pathogen.

The individual should immediately:

- Remove any contaminated clothing
- Allow wound to bleed freely and then cover lightly; needle stick injuries/wounds should not be squeezed
- Wound and skin exposure sites should be washed with soap and water
- If exposed area involves the eyes, nose or mouth, thoroughly flush well with water
- Report the incident to his/her immediate supervisor who should implement agency protocol
- Proceed **immediately** for a risk assessment to the closest hospital emergency department



STEP 2 ASSESS THE EXPOSURE RISK²

A risk assessment should be performed on the exposed person within two hours of exposure. Many factors contribute to the risk of transmission of a blood borne pathogen, including the following:

a. Body fluids involved

- body fluids <u>considered potentially infectious</u> include blood, serum, plasma, visibly bloody fluids, semen, vaginal secretions, rectal secretions, cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluid
- body fluids <u>NOT considered potentially infectious</u> for a blood borne pathogen include feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus, unless they are visibly bloody

b. Type of Injury/Exposure

- percutaneous potential risk if skin puncture or laceration by needle or sharp object; needle sharing
- mucosal potential risk if splash to mucous membranes (e.g., eyes, nose, mouth)
- cutaneous potential risk if contact through non intact skin (e.g., cuts, dermatitis)
- sexual activity potential risk with insertive or receptive, anal or vaginal intercourse

c. Inoculum size

• Increased risk with volume of infectious fluid involved, and with hollow bore vs. solid needle

d. Source person attributes

- Increased risk if known positive for HBV, HCV, or HIV
- Decreased risk if low viral load in the infectious fluid and the disease is well controlled consider current and past antiviral/antiretroviral use
- Increased risk of HIV transmission (8-12x higher) during the acute stage of HIV (first 6 months)

• Increased risk with presence of the following risk factors in the case of unknown HBV, HCV or HIV status (e.g., men who have sex with men, multiple sexual partners, injection drug user, tattoo/body piercing, history of incarceration, shared needles or other drug equipment, recipient of blood transfusion before 1986 for HIV or 1990 for HCV in Canada)²

e. Presence of sexually transmitted infections (in cases of sexual exposures)

Both the source and exposed individual are at increased risk of acquiring a blood borne pathogen if STI
present

Estimated risk of transmission:

Hepatitis B:

- 6-30% following percutaneous exposure to known infectious blood or body fluids
- In the case of a human bite where the skin is broken, the risk of transmission to the person who is bitten is unknown but is likely to be quite low since the concentration of HBV is 1000x lower in saliva than in blood

Hepatitis C:

• 3-10% following percutaneous exposure to known infectious blood or body fluids

HIV: See Table 1

• 0.23% (0.09% for mucous membrane exposure)²

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act ^{a,4}

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other ^b	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

^a Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

^b HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

The decision to recommend PEP is based on the assessment of the physician. Post-Exposure Prophylaxis to prevent infection following an exposure to blood or body fluids is available for HBV and HIV in hospital emergency departments.

3a) PEP Management - HBV EXPOSURE^{2,5}

Management of potential hepatitis B exposure is dependent on the risk of exposure to hepatitis B infected fluid (see Step 2), vaccination and immune status of the exposed individual, in addition to the serologic status of the source. See Step 4 for baseline testing for exposed person.

Do not delay management to wait for results of anti-HBs.

Note: Pregnant or breastfeeding women can receive the hepatitis B vaccine and the hepatitis B immune globulin.

- 1. For the **exposed individual who has documentation of IMMUNITY:** (anti-HBs > 10 IU/L after completing the 3-dose hepatitis vaccination or natural immunity from previous exposure):
 - No further action is required
- 2. For the exposed individual who is known to be non-immune or has incomplete vaccination:
 - **never been vaccinated** → consider HBIg (see below*) + 1 dose of vaccine (see below^)
 - anti-HBs < 10 IU/L after **completed one vaccine series** → consider HBlg* + 1 dose of vaccine^ (encourage completion of 2nd series and test for anti-HBs 1 to 6 months later)
 - anti-HBs < 10 IU/L after completed two vaccine series

 → consider HBIg * x 2, separated by 1 month
 - **previously received 1 dose Hep B vaccine** → consider HBlg* + 1 dose of vaccine[^] (encourage completion of series)
 - **previously received 2 doses Hep B vaccine** \Rightarrow 3rd dose of vaccine[^]; if anti-HBs titre unknown after 48 hours or < 10 IU/L, consider HBlg* and test for anti-HBs 6 months later; if titre is \ge 10 IU/L then consider as responder in future
- 3. For the exposed individual who is vaccinated (3 doses) with UNKNOWN antibody status:
 - 1 dose of vaccine[^] could be delayed if anti-HBs result known within 48 hours
 - When anti-HBs result becomes known and < 10 IU/L, consider HBIg* and test for anti-HBs
 6 months later
 - If anti-HBs ≥ 10 IU/L consider as responder in future

*Hepatitis B immune globulin (HBIg)²

- If source is known to be hepatitis B positive or high risk, it is recommended to give HBIg. If source is known to be hepatitis B negative or low risk, HBIg is not recommended
- When indicated, HBIg should be given as soon as possible, preferably within 24 hours after the exposure. Efficacy decreases substantially when it is given > 48 hours post-exposure, and effectiveness when administered after 7 days is unknown

- Dosage is 0.06 ml/kg body weight for older children and adults; total dose to be divided into two separate intramuscular administration sites. Dose should be repeated in one month in a known non-responder (e.g. anti-HBs < 10 IU/L after two complete hepatitis B vaccination series)
- Hospital blood banks can order HBIg from Ottawa Canadian Blood Services via fax 613 560-7199
 using Volume Expanders / Immune Globulins and S/D Plasma Order Form. For stat orders, call prior to
 faxing order to 613 560-7212

^Hepatitis B vaccine series²

- Doses should be administered at a site separate from HBIg if co-administered
- Completion of the series is encouraged in individuals who are given 1 dose of vaccine due to an exposure
- A second 3-dose series of the hepatitis B vaccination may be indicated in an individual who is non-immune (anti-HBs < 10 IU/L) after the first course

Note: The Canadian Immunization Guide (2016), offers further detailed information (figure 2 and 3)

Counselling and Follow-up

The non-immune exposed individual should be counselled:

• on the signs and symptoms of hepatitis that may occur within 6 weeks to 6 months after exposure (e.g., fatigue, loss of appetite, abdominal discomfort, jaundice, change in colour of urine and stool, rash, sore joints)

If the source is known, suspected, or found to be positive for HBsAg and the exposed individual is non-immune to Hepatitis B, the exposed individual should be counselled that for 24 weeks post exposure to:

- not donate blood, semen, tissues, or organs
- prevent sexual transmission (use of condoms, abstinence)
- avoid needle-sharing
- not share razors or toothbrushes

Follow-up Tests

- The non-immune individual should be evaluated at 6 months for possible seroconversion: HBsAq
- Hepatitis B antibodies (anti-HBs) should be obtained 1-2 months after completion of the hepatitis B vaccine series; if HBIg was given at the same time, anti-HBs testing should occur a minimum of 6 months after the HBIg dose

3b) PEP Management - HCV EXPOSURE²

There is no prophylactic treatment currently available for a person exposed to hepatitis C. Data does not support the use of immune globulin (Ig) or antiviral agents, and thus these agents cannot be recommended. In the absence of PEP against HCV, recommendations are to identify infection early and, if present, refer for evaluation for treatment options. Data suggests that early treatment of acute HCV infection with interferon is highly effective in curing HCV.²

Counselling and Follow-up

The exposed individual should be counselled:

• on the signs and symptoms of hepatitis that may occur within 6 weeks to 6 months after exposure (e.g., fatigue, loss of appetite, abdominal discomfort, change in colour of urine and stool, rash, sore joints)

If the source is known, suspected, or found to be positive for HCV, the exposed individual should be counselled that for 24 weeks post exposure to:

- not donate blood, semen, tissues, or organs
- prevent sexual transmission (use of condoms, abstinence)
- avoid needle-sharing
- not share razors or toothbrushes

Follow-up Tests^{2,3}

- HCV-RNA test at 6 weeks is recommended as it can identify acute infection within 2 weeks of
 exposure where the HCV serological window period is 5-10 weeks and it is estimated that 30% of
 acute infections may be missed if anti-HCV is the only marker of infection used during this time period
- HCV antibody at 4 and 6 months

3c) PEP Management - HIV EXPOSURE^{2,3}

Management of a potential HIV exposure is dependent on the risk for HIV transmission which varies with the nature and severity of the exposure (see table 1 on Estimated Per-Act Risk for Acquisition of HIV). HIV PEP usually consists of treatment with 2 to 3 antiretroviral drugs for 28 days. **Treatment should be started as soon as possible, ideally within 1 to 4 hrs of the exposure and no longer than 72 hours as efficacy declines rapidly with time.**²

If the source person's HIV serology is subsequently found to be negative, post-exposure prophylaxis can be discontinued and no further follow up for HIV testing is necessary.

** Consult with the Infectious Disease Physician (24 hr service) at the Ottawa Hospital (613) 737-8222 or at the Kingston General Hospital (613) 548-3232 as soon as possible if considering PEP.

The following PEP recommendations are outlined in the Alberta Guidelines for Non-Occupational,
Occupational and Mandatory Testing and Disclosure Act Post Exposure Management and Prophylaxis, 2015.

1. PEP is RECOMMENDED in the following exposures-when source is known to be HIV-positive³:

- Percutaneous injury (any)
- Mucous membrane OR non-intact skin exposure to blood or visible blood-stained bodily fluids
- Receptive or insertive anal or vaginal penetration without condom, and receptive oral penetration without condom, OR unknown sexual exposure (e.g., victim under influence of drugs/alcohol)

Note: In a source patient who is HIV positive, having an undetectable serum viral load dramatically reduces but does not totally eliminate HIV transmission. PEP should be considered.

2. PEP is RECOMMENDED in the following exposures - when source has unknown HIV status, however is high risk for HIV³:

- Percutaneous injury: IDU needle sharing; large bore needle; deep puncture; visible blood (fresh) on device/syringe
- Receptive anal or vaginal penetration, without condom OR unknown sexual exposure (e.g., victim under influence of drugs/alcohol)

3. PEP is GENERALLY NOT recommended for³:

- Percutaneous superficial injury or "cold" needle exposures (e.g., injuries from a needle found in the community) almost never require post-exposure prophylaxis but PEP may be considered in exceptional circumstances (e.g., fresh blood on device or in syringe, deep puncture/injury)
- Mucous membrane OR non-intact skin exposure to blood or visibly blood stained fluids when source is high-risk for HIV OR when source has unknown HIV status but PEP may be considered in exceptional circumstances (e.g., extensive mucosal/non-intact skin exposure to blood)
- Insertive oral sex—unless additional factors increase risk (e.g., source person is HIV + with high viral load; oral lesions; known blood exposure; presence of genital ulcers/STIs)

4. PEP is NOT recommended for3:

- Mucous membrane exposure to non-blood containing body fluids
- Intact skin exposure to blood or blood-stained body fluid
- Anal or vaginal or oral penetration with intact condom

Counselling and Follow-up²

The exposed individual should be counselled:

- on the signs and symptoms of HIV infection that may occur within 2-14 weeks after exposure (e.g., "flu-like" symptoms, weight loss, skin rash, fever, lymphadenopathy, fatigue)
- on the benefits and side effects of anti-retroviral PEP, including the importance of adherence to prevent PEP failure
- to avoid pregnancy and breastfeeding if the source is known or suspected to be positive for HIV

If the source is known, suspected, or found to be HIV positive, the exposed individual should be counselled that for 12 weeks post exposure to:

- not donate blood, semen, tissues, or organs
- prevent sexual transmission (use of condoms, abstinence)
- avoid needle-sharing
- not share razors or toothbrushes

Follow-up Tests

3 weeks: Serum creatinine (for potential PEP toxicity), HIV Ag/Ab

6 weeks: HIV Ag/Ab 12 weeks: HIV Ag/Ab

A confirmatory assay should be done to confirm a diagnosis of HIV infection if test result is positive.

STEP 4 BASELINE TESTING^{2,6}

Since serologic testing of the source patient for HBV, HCV and HIV is the most reliable method to assess the risk of exposure, this is strongly recommended. Ascertain if the exposed individual is willing to be tested for antibody to HBV, HCV and HIV. If the exposed individual is not willing to be tested, do not test the source person unless they have a separate indication for testing.

Source person (if available)²

The source person should be informed of the incident, and asked to undergo testing. Informed consent must be obtained and documented including consent for disclosure of results to the exposed individual's physician and their own physician.

If the source person does not consent to testing and is at epidemiological risk for infection with HBV, HCV or HIV, follow the protocol for a positive source. However, an application can be made to the medical officer of health (MOH) requiring **mandatory blood testing** by the source person if the exposure occurred:

- as a result of being a victim of crime
- · while providing emergency health care services or emergency first aid to the person or
- in the course of his or her duties, if the person belongs to an identified group of individuals, including:
 - persons who are employed in a correctional institutions, place of open custody or place of secure custody
 - police officers, civilian employees of a police service, First Nations constables and auxiliary members of a police service
 - firefighters (including volunteer firefighters)
 - paramedics and emergency medical attendants
 - members of the College of Nurses of Ontario
 - paramedic students engaged in field training

The application process can be found on the Ministry of Community Safety and Correctional Services website⁶

Tests:

- HIV Ag/Ab
- Hepatitis B surface antigen (HBsAg)
- Hepatitis C antibody (HCV Ab); if positive, test for HCV RNA

Source person (if not available)

If the source person is unknown or cannot be tested, consider their likelihood of having a blood borne pathogen based on local epidemiology, e.g., what is the prevalence of infection in this population? Does the source have risk factors for infection?

Exposed individual²

Note: Initiation of post-exposure prophylaxis for HBV or HIV exposure should not be delayed pending source test results.

Obtain informed consent for testing. If the exposed individual is not willing to be tested for HIV, then HIV PEP should not be initiated.

Tests:

- HIV antibody (HIV Ag/Ab)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B surface antibody (anti-HBs)
- Hepatitis B core antibody (anti-HBc)
- Hepatitis C antibody (HCV Ab); if positive, test for HCV RNA
- If starting on HIV PEP: CBC, serum creatinine, ALT
- Pregnancy test (ß-HCG)
- STI testing (for sexual exposures)

If BASELINE result in EXPOSED individual is²:

Positive for HBsAg, HCV or HIV antibody

Give appropriate counselling, provide medical referral, and follow appropriate policies

Negative for HBsAg, HCV or HIV antibody AND

The source person's test results are negative:

- No further testing of the exposed for HIV infection is indicated if the source person is HIV seronegative
 and has no clinical evidence of recent HIV infection. The likelihood of the source person being in the
 "window period" of HIV infection (the interval between HIV infection and the detection of antibodies
 to HIV) in the absence of symptoms of acute retroviral syndrome is low. The average window period
 with the 4th generation tests are less than 3 weeks, but can be up to 3 months
- Encourage the exposed person to complete the 3-dose vaccine for hepatitis B, if not already immune

The source test result is positive or unknown:

• Follow the PEP management procedure for HBV, HCV and/or HIV exposure

STEP 5 WSIB REPORTING

In cases where HIV infection is suspected, the employer must report the exposure to the <u>Workplace Safety Insurance Board Ontario</u> and to the Ministry of Labour if post-exposure prophylaxis (PEP) is given. As well, employers who do not follow a surveillance protocol (a procedure for testing, monitoring and maintaining records) must report when a worker has been exposed to, or is suspected of having been exposed to, an infectious disease through a needle stick injury.⁷

If seroconversion occurs after a documented exposure to HBV, HCV, or HIV, and the exposure occurred in an occupational setting, this must be reported to the Joint Health & Safety Committee, Workplace Safety and Insurance Board (WSIB), the Medical Officer of Health (Public Health), Ministry of Labour and a referral should be made for medical evaluation and consideration of antiviral therapy.²

REFERENCES

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